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# Supreme Court of the United States

OCTOBER TERM, 1992

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WILLIAM DAUBERT and JOYCE DAUBERT, Individually and as Guardians Ad Litem for JASON DAUBERT, and ANITA DE YOUNG, Individually and as Guardian Ad Litem for ERIC SCHULLER,
*Petitioners*,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
*Respondent.*

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**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

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## BRIEF OF THE AMERICAN MEDICAL ASSOCIATION, AMERICAN MEDICAL ASSOCIATION/SPECIALTY SOCIETY MEDICAL LIABILITY PROJECT,

**(Additional *Amici* Listed on Inside Cover)**

## AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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AMERICAN ACADEMY OF ALLERGY AND IMMUNOLOGY, AMERICAN ACADEMY OF DERMATOLOGY, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY OF NEUROLOGY, AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS, AMERICAN ACADEMY OF PAIN MEDICINE, AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, AMERICAN COLLEGE OF PAIN MEDICINE, AMERICAN COLLEGE OF PHYSICIANS, AMERICAN COLLEGE OF RADIOLOGY, AMERICAN SOCIETY OF ANESTHESIOLOGISTS, AMERICAN SOCIETY OF PLASTIC AND RECONSTRUCTIVE SURGEONS, AMERICAN UROLOGICAL ASSOCIATION, AND COLLEGE OF AMERICAN PATHOLOGISTS

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## QUESTION PRESENTED

*Amici curiae* will address the following question:

Whether, under Rule 702 of the Federal Rules of Evidence, a properly qualified expert in a scientific subject must be permitted to testify in federal court, even though the testimony proffered lacks a foundation in established scientific knowledge or is not based upon a valid scientific methodology.

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## INTEREST OF *AMICI CURIAE*

*Amicus* American Medical Association (AMA) is a private, voluntary, nonprofit organization of physicians. The AMA was founded in 1846 to promote the science and art of medicine and the improvement of public health. Today its 280,000 members—over half of all physicians currently licensed to practice medicine—practice in all fields of medical specialization.

*Amicus* American Medical Association/Specialty Society Medical Liability Project (the "Project") was formed in 1986 as a coalition of the American Medical Association, the Council of Medical Specialty Societies, and over 30 national medical specialty societies to present the views of organized medicine on issues related to medical professional liability. The *amici* organizations joining this brief individually are the American Academy of Allergy and Immunology, American Academy of Dermatology, American Academy of Family Physicians, American Academy of Neurology, American Academy of Orthopaedic Surgeons, American Academy of Pain Medicine, American Association of Neurological Surgeons, American College of Obstetricians and Gynecologists, American College of Pain Medicine, American College of Physicians, American College of Radiology, American Society of Anesthesiologists, American Society of Plastic and Reconstructive Surgeons, American Urological Association and the College of American Pathologists.[1]

The issue presented by the holding below is of great importance to the many physicians represented by *amici* and the patients they serve. The issue is of significance to *amici* because standards for professional conduct that are established on a case-by-case basis in the courtroom can have an immediate and lasting impact on medical practices and the price and availability of medical products and services. More broadly, the medical profession

[1] Descriptions of the individual specialty societies that have joined this brief are included in the attached Appendix.



has a stake in preserving and promoting the integrity and legitimacy of medical and other scientific research. In addition, the standards for scientific testimony in the courtroom are of concern to the medical profession because it has an ethical duty to assist in the administration of justice. See AMA, *Current Opinions of the Council on Ethical and Judicial Affairs* § 9.07 (1986). Accordingly, *amici* wish to assist the Court properly to resolve the issue presented.[2]

## STATEMENT

*Amici* adopt the statement of the case as set forth by respondent in its brief in this Court and emphasize the following facts:

Summary judgment was granted to respondent in this case because the district court held that petitioners lacked sufficient evidence that Bendectin caused birth defects. Pet. App. A5. The judgment therefore rested upon the holding that the expert testimony proffered by petitioners lacked a sufficient scientific foundation to be admissible. *Id.* Respondent, by contrast, produced a wealth of scientific evidence that Bendectin, one of the most scientifically tested drugs in history, does not cause birth defects. *Id.* at A2. Over 30 published epidemiological studies have been performed to determine whether Bendectin is a teratogen. None of these studies has ever found any statistically significant correlation between the use of Bendectin and an increase in the incidence of limb defects. *Id.*

The Ninth Circuit held that *in vitro* and *in vivo* animal tests and chemical structure analyses, upon which petitioners' experts sought to base their opinions, did not provide a sufficient scientific foundation for an expert opinion that Bendectin causes birth defects. *Id.* at A3. Moreover, the court of appeals also concluded that peti-

[2] Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the Clerk of the Court.

tioners' experts, in "reanalyzing" existing epidemiological evidence, had simply manipulated the data in existing studies in a scientifically unprincipled way (solely in anticipation of litigation) and had not subjected such "reanalysis" to the scrutiny of other scientists by peer-reviewed publication. *Id.* at A4-A5. Thus, the court below concluded that petitioners lacked any admissible expert evidence on the element of causation and summary judgment was affirmed. *Id.*

## SUMMARY OF ARGUMENT

### I.

A. Rule 702 of the Federal Rules of Evidence does not permit the admission into evidence of all opinions that are "scientific," in the sense that a scientific issue is the subject of the opinion. See, *e.g.*, *United States* v. *Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985). Rather, pursuant to the language of Rule 702 itself, a scientific expert can only testify to "knowledge" that is "scientific."

B. "Scientific knowledge" is that body of knowledge that has been learned or developed in accordance with rigorous scientific methodology. The scientific method involves replicable, empirical testing of hypotheses. Hypotheses that cannot be corroborated by such testing are discarded. Hypotheses that are repeatedly corroborated are labelled "theories" and generally accepted as valid. Medical knowledge is one kind of scientific knowledge. It is acquired through the application of the scientific method to questions concerning the effects of various interventions on human health.

Medical researchers acquire scientific knowledge through laboratory investigation, studies of animal models, human trials, and epidemiological studies. Such empirical investigations frequently demonstrate *some* correlation between the intervention studied and the



hypothesized result. However, the demonstration of a correlation does not prove the hypothesized result and does not constitute scientific knowledge. In order to determine whether the observed correlation is indicative of a causal relationship, scientists necessarily rely on the concept of "statistical significance." The requirement of statistical reliability, which tends to prove that the relationship is not merely the product of chance, is a fundamental and indispensable component of valid scientific methodology.

C. Judges are capable of distinguishing opinions based upon scientific knowledge from those opinions that are not based upon scientific knowledge, without considering the substance of an expert's opinion. In general, the publication of a study on a particular hypothesis in a peer-reviewed journal indicates that the study is based upon a scientific methodology. Moreover, the complete absence of any peer-reviewed publication supporting a particular hypothesis—particularly one that has been tested numerous times—is powerful evidence that testimony propounding that hypothesis lacks sufficient scientific merit to permit its introduction into evidence.

### II.

There is good reason—beyond achieving a just outcome in a particular case—to require testimony of a proffered expert to be based upon scientific knowledge. Recent history demonstrates that legal judgments based upon opinions not developed in accordance with scientific methodology have caused manufacturers to withdraw a number of safe and effective vaccines and drugs, including Bendectin and various contraceptives, from the market. Such legal judgments also have significantly stymied innovation in pharmaceutical and vaccine research. Finally, such judgments have forced certain medical specialists to discontinue providing certain services, particularly

obstetrical care. The withdrawal of beneficial products and medical services has a serious and entirely unwarranted adverse effect on public health. By excluding evidence that is not grounded in the scientific method, Rule 702 promotes the factfinding function of the legal process and simultaneously avoids doing violence to the values that undergird science.

### III.

The "reanalysis" of the epidemiological studies at the core of the petitioners' proof of causation was neither published in any peer-reviewed journal nor otherwise developed in accordance with the scientific method. Accordingly, the testimony of petitioners' experts was not based on "scientific knowledge." In light of the overwhelming epidemiological evidence concluding that Bendectin is not teratogenic, testimony based upon such "reanalysis" properly was excluded under Rule 702.

## ARGUMENT

### I. RULE 702 OF THE FEDERAL RULES OF EVIDENCE EMBODIES A REQUIREMENT THAT EXPERT OPINIONS THAT LACK A LEGITIMATE SCIENTIFIC OR MEDICAL BASIS ARE NOT ADMISSIBLE.

Rule 702 limits expert testimony to "scientific knowledge" that will assist the jury in determining a fact in issue. This does not mean, as petitioners suggest, that any testimony by a qualified expert that relates to a scientific topic and that is relevant to the issues in the case must be admissible in federal court. Rather, expert testimony is based on scientific knowledge, and hence admissible, only when it is based on information derived through the application of the scientific method and not on idiosyncratic theories, calculations or beliefs. The district courts are capable of identifying testimony based on such knowledge, and are obligated by Rule 702 to



exclude all other purportedly scientific testimony. In the medical context, this requires that courts determine that an expert will rely on well-designed clinical or epidemiologic studies, and that they exclude any proffered opinion that lacks such a foundation.

#### A. Rule 702 Requires That, In Order To Be Admissible, Expert Scientific Opinion Must Be Based In "Scientific Knowledge."

Rule 702 provides that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. By use of the word "thereto," the Rule makes clear that an expert witness may only testify to "scientific, technical, or other specialized knowledge" that will "assist the trier of fact." At issue in this case is the limitation inherent in the requirement of Rule 702 that admissible expert testimony be based upon "scientific knowledge." [3]

One reason to give the term "scientific knowledge" substantial meaning as a threshold requirement is that expert testimony is accorded special treatment under the Federal Rules of Evidence and existing practice. Experts are "qualified" by the court in the presence of the jury and the jury receives special instructions on the expert's status.[4] Expert witnesses also are exempt from

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[3] Expert testimony may be based upon "technical or other specialized knowledge" as well as "scientific knowledge." "Scientific" experts are professionals recognized as scientific, such as physicians. "Technical" experts may testify to non-scientific man-made rules, such as accounting standards. As the advisory notes suggest, "other specialized" experts include such people as bankers or appraisers who testify about land values. Fed. R. Evid. 702, Advisory Committee's Note.

[4] *See, e.g.*, 1 E. Devitt *et al.*, *Federal Jury Practice and Instructions* § 14.01, at 403 (1992) (jury instructed that expert, unlike

many of the evidentiary restrictions of the Federal Rules: experts need not testify from personal knowledge, they need not testify to the foundation for their opinions, and the bases for their opinion need not be admissible. See Fed. R. Evid. 703, 705. Moreover, experts, unlike other witnesses, generally may testify directly on the "ultimate issues" to be decided by the jury. Fed. R. Evid. 704.

Partially in recognition of the special status of experts, Rule 702 establishes a higher standard for the admissibility of expert testimony, especially testimony by scientific experts, than mere relevance. See, *e.g.*, *United States* v. *Downing*, 753 F.2d 1224, 1235 (3d Cir. 1985) ("we believe that [Rule 702] necessarily implies a quantum of reliability beyond that required to meet a standard of bare logical relevance"); *United States* v. *Williams*, 583 F.2d 1194, 1198-99 (2d Cir. 1978) (similar assessment of factors relating to reliability of scientific evidence), *cert. denied*, 439 U.S. 1117 (1979); see also Fed. R. Evid. 402 ("All relevant evidence is admissible, except as otherwise provided by the Constitution . . . by Act of Congress, by these rules, or by other rules prescribed by the Supreme Court pursuant to statutory authority"). Thus, evidence that, according to Ptolemaic methodology, the sun revolves around the earth might be "relevant" (within the meaning of Rule 401) in a particular case, but an otherwise qualified astrophysicist may not so testify because such testimony does not satisfy the requirement that expert testimony be based upon "scientific knowledge." [5]

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other witnesses, is permitted to testify to "opinion" because "such knowledge or experience may be of assistance to you in understanding some of the evidence or in determining a fact"); *see also Manual of Model Criminal Jury Instructions for the District Courts of the Eighth Circuit* § 4.10 (1992); United States Eleventh Circuit District Judges Association, *Pattern Jury Instructions for Civil Cases*, Instruction No. 5.2, at 13 (1990).

[5] The example in the text illustrates the basic principle, but it does not adequately illustrate the problem posed by the evidence in this case. Most jurors probably have formed an opinion concerning the revolution of the earth around the sun, and therefore the admission of testimony to the contrary is not likely adversely to affect the factfinding process. By contrast, whether a drug such as Bendectin causes birth defects is a matter that the ordinary juror will know nothing about. Accordingly, it is only reasonable to ask jurors to make such a scientific judgment when the various scientific hypotheses presented to them have a sufficient basis in scientific method to create a triable dispute.



While the lower courts have universally agreed that expert scientific testimony must satisfy a higher threshold standard than mere relevance, they differ in defining that higher standard of admissibility. One alternative, which most courts have adopted, is the rule in *Frye* v. *United States*, 293 F. 1013 (D.C. Cir. 1923). Under *Frye*, the methodology used by the expert in deriving the opinion must be "generally accepted" by the relevant scientific community. Another alternative, accepted in some form or another by other courts, is to consider various attributes of the expert's methodology and weigh the efficacy of the testimony against the risk of confusing the jury. *Downing*, 753 F.2d at 1237-41; *Williams*, 583 F.2d at 1198-99. The language of Rule 702 itself, however, suggests a somewhat different standard—not only must the opinion be relevant (under Fed. R. Evid. 401), but the opinion must be based (according to Fed. R. Evid. 702) upon "scientific knowledge."

The requirement that an expert opinion must be based in "scientific knowledge" does not simply mean that the subject matter of the testimony must be scientific—*e.g.*, medicine or chemistry or physics. Rather, the limitation imposed by the term "scientific knowledge" requires that the content of the expert's testimony must be developed in accordance with scientific methodology. In particular, the use of the term "knowledge"—rather than "evidence" or "testimony"—underscores the requirement that an expert's testimony be developed in conformance with the rigorous standards of replicable experimentation and re-

porting that are the hallmarks of the scientific method. Only adherence to accepted scientific methodology can produce "knowledge"—*i.e.*, a deduction based upon empirical evidence that can be reproduced, challenged, accepted or built upon by other scientists.[6]

In sum, Rule 702, by its terms and structure, requires that expert testimony satisfy a threshold standard higher than mere relevance.[7] At a minimum, the use of the term "scientific knowledge" should be read to impose a requirement that the content of expert scientific testimony be derived from information developed in accordance with the scientific method. Excluding evidence that does not meet these standards promotes the factfinding function of the legal process and simultaneously avoids doing violence to values of "truth" that undergird science.

### B. "Scientific Knowledge" Within The Meaning Of Rule 702 Is Knowledge Derived From The Application Of The Scientific Method.

There is no question that, at any given time, qualified scientists may disagree about the appropriate answer—the most likely answer—to a particular scientific question. Scientific knowledge is not monolithic, and new scientific discoveries and developments are proceeding at a pace that precludes identification of a simple, uniform body of "knowledge." Nevertheless, there is a fundamental and widely accepted distinction between opinions that are based upon scientific knowledge and those that are not: An opinion is only based upon scientific knowledge if it is developed in accordance with the scientific method. Those are the only opinions that Rule 702 permits to be presented to the jury.

1. Scientific knowledge is the body of knowledge that has been developed through application of the scientific method. This method involves empirical testing of a hypothesis. If a hypothesis is contradicted by experimentation (or consistently fails to be corroborated), it is discarded and a new hypothesis must be developed. If a hypothesis is repeatedly corroborated by empirical testing, it is labelled a "theory" and generally accepted as valid. In principle, no scientific theory is ever definitively confirmed because it is always possible that an empirical test will someday demonstrate the theory to be incorrect. As a practical matter, however, some theories are so thoroughly tested that they become virtually incontrovertible. See generally National Academy of Sciences *et al.*, 1 *Responsible Science: Ensuring the Integrity of the Research Process* 36-40 (1992); K. Popper, *The Logic of Scientific Discovery* (1959).

In addition to proceeding from a scientific framework, the development of scientific knowledge requires that testing be conducted, and scientific evidence be developed, in accordance with techniques that science has determined over time to provide reliable and replicable data. Scientific inquiry demands the "pursuit of objective knowledge gleaned from observation." J. Neale & R. Liebert, *Science and Behavior: An Introduction to Methods of Research* 7 (1980). Thus, the validity of any scientific theory depends entirely on a reviewable *empirical* foundation. See J. Monahan & L. Walker, *Social Science in*

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[6] Two experts may, for example, reach the same conclusion about the identity of a person, one using DNA fingerprinting, and the other using alchemy. Only the first expert would be able to testify on the basis of "scientific knowledge." The other would be able to testify only on the basis of speculation and non-scientific belief.

[7] To satisfy Rule 702, expert testimony also must "assist the trier of fact." This requirement of "helpfulness" frequently arises as an issue in criminal cases. In that context, the prosecution often seeks to introduce technologically advanced methods of identification or investigation—such as "DNA fingerprinting"—into evidence. Such methods, while generally based on scientific knowledge, may or may not be sufficiently reliable or accurate to assist the jury. *See, e.g., United States* v. *Jakobetz*, 955 F.2d 786 (2d Cir.) (DNA "fingerprinting"), *cert. denied*, 113 S. Ct. 104 (1992). If a method is not sufficiently accurate, or the predictions a methodology generates are too speculative, then the testimony should be excluded as not helpful to the trier of fact.

*Law* 33-35 (1985); 1 J. Ziskin, *Coping with Psychiatric and Psychological Testimony* 65 (3d ed. 1981). Absent some accessible (usually published) deduction from a body of empirical evidence, a theory cannot be considered scientific. See Neale & Liebert, at 7, 14 ("The scientific approach requires that all claims be exposed to systematic probes").

Conventional scientific method requires the researcher to identify a means of observing events that permits the hypothesis to be supported or unsupported by the collected data. Hypotheses are framed in terms of the relationship between two variables. For instance, a scientist, in attempting to prove a connection between liver cancer and consumption of coffee, would compare the incidence of liver cancer in a group that did not drink coffee with the incidence in a group that did.

Obviously, there can be numerous causes of liver cancer. Therefore, it will be necessary for the scientist to collect a wide range of empirical data concerning both individuals with liver cancer and individuals without liver cancer and to analyze, using rigorous statistical techniques, the various relationships between the observable characteristics of these individuals and the incidence of liver cancer. The scientist through publication then explains to the scientific community precisely how the data were collected, how the data were analyzed statistically and whether the ultimate hypothesis is supported by the available empirical evidence at a sufficiently high level of confidence to warrant concluding that the relationship between the two variables is not merely the product of chance (or of an independent "confounding" variable, such as heredity). See *Responsible Science*, at 46-64; W.I.B. Beveridge, *The Art of Scientific Investigation* (1957); E. Wilson, Jr., *An Introduction to Scientific Research* (1952).

This methodology develops scientific knowledge by demonstrating that the hypothesized relationship is or is



not supported empirically. If the number of studies reflecting a negative conclusion increases, the confidence in the conclusion increases significantly, causing scientists to discard the hypothesis. G. Friedman, *Primer of Epidemiology* 2-3 (2d ed. 1980). Alternatively, repeated studies also can provide evidence that a relationship between two events does exist.

Finally, scientific method depends significantly upon the peer review process. It requires the scientist to devise methods of data collection that are replicable and to explain precisely how the scientist performed the experiment. Peer reviewers then can analyze the methods and identify potential flaws in the techniques, in the data, or in the statistical methods employed. Research that satisfies the rigors of peer review thus provides assurances that the "knowledge" derived from that research is "scientific." See *Responsible Science*, at 56-59; D. Hull, *Science as Process* (1988).

2. This case specifically involves the application of Rule 702 in the context of medical care. Medical knowledge is the form of scientific knowledge that addresses questions concerning the effects of various interventions on human health. Like other scientists, physicians form hypotheses, test those hypotheses through empirical experimentation, and, based on the results, either discard their hypotheses or build theories. See K. Rothman, *Modern Epidemiology* 7-21 (1986). Medical researchers gather scientific knowledge through laboratory investigations, studies of animal models and, when a particular therapy (*e.g.*, a drug or vaccine) has demonstrated sufficient promise, clinical testing in human subjects. The theories developed through medical testing usually are published in peer-reviewed journals, where they may be studied, questioned or verified by other investigators. A. Relman, *Publishing Biomedical Research: Rules and Responsibilities*, Hastings Center Rep. at 23 (May/June 1990). See *infra*, at 19-21.

The prototypical clinical trial is randomized and "double blind." In such a trial, patients are randomly assigned either to a "treatment" or "control" (placebo) group, and neither the investigator nor the patient knows to which group the patient has been assigned until the experiment has been completed. C. DeAngelis, *An Introduction to Clinical Research* 62-72 (1990).[8] In addition to clinical trials, medical researchers gather scientific information from epidemiological studies, in which they use various statistical methods to determine whether the incidence of a particular disease correlates with other factors. See Friedman, at 2.

As with clinical trials, epidemiological studies generally involve a comparison of a "control" population, which does not feature the variable to be tested, and another group, which does. For example, in this case, the relevant studies concerning the relationship between the use of Bendectin by pregnant women and limb defects in children compared the incidence of birth defects in women who took Bendectin and in women who did not. See J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (describing Bendectin studies).

Medical studies, whether clinical trials or epidemiologic studies, frequently demonstrate *some* correlation between the action studied (*e.g.*, the ingestion of a drug) and the hypothesized result (*e.g.*, a decrease in the size of a tumor). To determine whether the observed correlation is not due to chance, medical scientists rely on the concept of "statistical significance." A "statistically significant" correlation is generally considered to be one in which statistical analysis suggests that the observed relationship is not the result of chance. A statistically signifi-

[8] *See also* C. Oyster *et al., Introduction to Research: A Guide for the Health Science Professional* 55-65 (1987); C. Meinert & S. Tonascia, *Clinical Trials: Design, Conduct, and Analysis* 65-70 (1986).



cant correlation does not "prove" causation, but in the absence of such a correlation, scientific causation clearly is not proven.[9] See generally S. Selvin, *Statistical Analysis of Epidemiologic Data* 17-20 (1991).

Rule 702, by incorporating the term "scientific knowledge," is most naturally read to embrace this common understanding of what that term means. Accordingly, the Rule seems plainly to require district courts to make an initial judgment concerning the nature of the knowledge underlying a particular expert's testimony. Although that initial scrutiny is vital to the proper application of Rule 702, it should not impose a significant burden on the district courts.

### C. Courts Are Capable Of Distinguishing Opinions Based Upon Valid Scientific Knowledge And Methodology From Opinions That Lack A Scientific Basis And Must Exclude The Latter From Evidence.

This Court's announcement of a rule interpreting Rule 702 to limit expert testimony on "scientific" matters to those opinions and facts based upon scientific knowledge would not impose an unworkable burden on litigants or

[9] It is misleading to compare the 95% confidence level used in empirical research to the 51% level inherent in the preponderance of the evidence standard. *See generally* D.H. Kaye, *Apples and Oranges: Confidence Coefficients and the Burden of Persuasion*, 73 Cornell L. Rev. 54-77 (1987). The distinction lies in the difference between statistical association and legal causation (proximate cause). A plaintiff need only demonstrate by a preponderance of evidence that a product was the proximate cause of his or her particular injury. He or she must, however, demonstrate with a much higher degree of certainty that there is a statistical association between use of the product and the type of injury that he or she suffered. Thus, the courts correctly have recognized that scientific studies should be statistically significant before being allowed into evidence. *See Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159, 1161-62 (D.C. Cir. 1990); *see generally Marder* v. *G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986), *aff'd without op.*, 814 F.2d 655 (4th Cir. 1987); *In re Agent Orange*, 597 F. Supp. 740, 785 (E.D.N.Y. 1984).

upon the district courts. Although most judges are not scientists, judges are fully capable of distinguishing expert testimony that is based upon "scientific knowledge" from expert testimony that is not. In some cases, this may simply require the courts to identify a universally accepted theory as the basis of the testimony. In other cases, where a legitimate scientific debate exists, the proposed rules would require the trial judge to determine whether the proffered testimony has a foundation in scientific knowledge—*i.e.*, a scientific methodology.

On some issues, a scientific or medical theory is essentially beyond dispute because the theory has been corroborated by testing so many times that scientists have a very high confidence in its validity. For example, scientists are universally satisfied that the earth revolves around the sun, not vice versa. Views such as the plainly constitute "scientific knowledge," and can easily be recognized by the courts. Where an expert opinion rests upon a generally accepted scientific theory, the testimony should be admissible.

In other cases, however, the disputed issue cannot be explained by any single generally accepted scientific theory. Instead, both sides will offer to explain the disputed fact by means of conflicting expert testimony. In such cases, a trial judge can still determine whether the opinion proffered by a scientific expert is truly the product of scientific knowledge. To do so, the trial court must determine only whether the expert relied upon the scientific method in reaching his or her opinion. The court need not, at any time, consider the substance or conclusion of the expert's opinion. Indeed, two competing expert opinions in a given case can both be "scientific," and the court in that case need not decide which is correct. It need only determine whether both approaches are the product of a proper scientific methodology.[10]

[10] The adversary process of the law will never be a perfect vehicle for resolving scientific disputes. Neither judges nor juries are particularly well suited to deciding differences of scientific opinion. However, the problems inherent in the capacity of the judicial process to resolve such disputes will only be exacerbated if the rules do not provide some threshold check on what expert opinions are admissible.



To determine whether testimony is the product of scientific methodology, courts should require an expert to explain his or her methods so that it can assess them in light of Rule 702. In some cases, a pretrial hearing (see Fed. R. Evid. 104(a) and (b)) or voir dire may be required. The Rules also permit the court to appoint its own expert, who can assess whether proffered testimony constitutes "scientific knowledge." Fed. R. Evid. 706. In addition, the courts can and should look to whether the facts supporting the evidence have been published in peer-reviewed journals. The mere fact that research has not been subjected to peer review does not render unscientific that which otherwise conforms to scientific standards. Nonetheless, peer review usually assures that knowledgeable experts in the field have already read a paper with critical eyes, and thus it can play an important role in the court's Rule 702 determination.

Peer review cannot assure the ultimate validity of an article's conclusions. Reviewers may not, for example, detect fraud or carelessness in data or other sorts of errors that are not readily apparent. Peer review, however, is a significant indicator that an article is "scientific," because reviewers are well-positioned to identify conceptual departures from the scientific method. "Good peer reviewed scientific journals should provide their readers with reports of the best available research, free of obvious major flaws." A. Relman & M. Angell, *How Good Is Peer Review?*, 321 New Eng. J. Med. 827, 828 (1989).

Moreover, it is implicit within the scientific method's requirement of reproducibility that results will in fact be reproduced and confirmed by other scientists.

Peer review and publication further that process, which makes it more likely that fraud or other shortcomings will be detected. See D. Hull, *Science as Process* (1988); J. Ziman, *Reliable Knowledge* (1978). Thus, publication in a peer-reviewed journal should constitute significant evidence that the research adhered to "scientific" standards, as Rule 702 requires. The absence of peer review, particularly in circumstances in which the theory is novel or contrary to the weight of the scientific research, is a strong indication that the testimony lacks a scientific foundation.

In sum, district courts can determine whether proffered expert testimony is sufficiently grounded in scientific knowledge to warrant its admission into evidence under Rule 702. To do so, they must determine whether the testimony relies on information derived through application of the scientific method. In general, this requires that they determine that the testimony is based on rigorously controlled, reproducible scientific studies. In the medical context, they must determine that the expert will rely on well-designed clinical or epidemiologic studies. Publication of information in a peer-reviewed journal is a strong indication that that information reflects "scientific knowledge," whereas the absence of publication is indication to the contrary. Where, as here, there has been ample opportunity for publication, the conclusion is inescapable that expert testimony relying on information that has not been peer-reviewed has no basis in "scientific knowledge."

## II. THE ADMISSION OF "EXPERT" OPINIONS THAT DO NOT HAVE A BASIS IN SCIENTIFIC KNOWLEDGE HAS AN ADVERSE EFFECT ON MEDICAL PROFESSIONALS, THEIR PATIENTS, AND SOCIETY.

In addition to the plain language of Rule 702, sound public policy counsels that expert testimony should be limited to opinions based upon scientific knowledge. Obviously, the introduction of evidence not grounded in scientific knowledge may lead to inequitable judgments in individual cases. *Cf.* Fed. R. Evid. 102 (the Federal Rules of Evidence should be construed to further the goal of ascertaining the truth and providing a just determination of a case). But, more fundamentally, permitting civil damage actions to be decided on the basis of opinions not grounded in scientific knowledge will, over time, have a detrimental effect on the medical profession and the patients it serves.[11]



Indeed, examples from recent history demonstrate that as a result of legal judgments based upon invalid medical or scientific opinions, medical professionals have been deprived of a number of valuable tools. "Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." AMA Board of Trustees, "Impact of Product Liability on the Development of New Medical Technologies" ("AMA Report"), at 1 (June 1988). In addition, medical professionals have themselves been compelled to modify their practices or to stop providing certain services because of the threat of liability imposed by such judgments. By forcing these valuable products and services off the market, legal judgments not grounded in science ultimately have an adverse effect

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[11] There is no question that standards of tort liability are intended to have, and do have, an effect on behavior. *See* D. Hughes *et al., Obstetrical Care for Low-Income Women*, in II *Medical Professional Liability and the Delivery of Obstetrical Care* 59, 73-74 (V. Rostow & R. Bulger eds., 1989); A. Relman, *Medical Professional Liability and the Relations Between Doctors and Their Patients*, in II *Medical Professional Liability*, at 97, 99-103; P. Bell, *Legislative Intrusions into the Common Law of Medical Malpractice: Thoughts about the Deterrent Effect of Tort Liability*, 35 Syracuse L. Rev. 939, 971 (1984); see also *Browning-Ferris Indus. Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring) ("The threat of . . . [unfounded punitive damage] awards has a detrimental effect on the research and development of new products").

on the health of patients. See, *e.g.*, D. Hughes *et al.*, *Obstetrical Care for Low-Income Women*, in II *Medical Professional Liability and the Delivery of Obstetrical Care* 59, 73-74 (V. Rostow & R. Bulger eds., 1989).

Bendectin itself is a prime example of a beneficial drug, which has been approved as "safe and effective" by the Food and Drug Administration,[12] but which is no longer available to physicians and patients because of liability imposed on the basis of unscientific expert testimony. More than 30 scientific studies have been conducted to determine whether any statistically significant correlation exists between the use of this drug and limb defects. No study has demonstrated such a correlation. See J. Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 Hastings L.J. 301 (1992) (summarizing the findings).

Nevertheless, women suffering from morning sickness cannot purchase Bendectin (or any other treatment)—despite the fact that severe morning sickness can have significantly adverse medical side-effects. Nausea and

[12] The FDA conducts extensive pre-approval testing, in three "phases," on every new drug. Phase I principally involves testing for toxic side-effects on approximately 20 to 80 subjects. Phases II and III consist of "controlled clinical studies" on hundreds or even thousands of human subjects. 21 C.F.R. § 312.21. These clinical trials must be "well-controlled" and have enough subjects so that they are "scientifically valid." *Id.*

The FDA determined Bendectin to be "safe" in 1956. Because of public concerns about the safety of the drug, the FDA's Fertility and Maternal Health Drugs Advisory Committee—an independent expert panel composed of physicians, scientists and a consumer representative, and advised by scientists from the National Institutes of Health—reviewed this determination in 1980. Following public hearings and an extensive review of the evidence, this committee concluded that there is no increased incidence of birth defects resulting from exposure to Bendectin. The FDA announced its agreement with this finding, and the agency has stood by it ever since. *See Richardson* v. *Richardson-Merrell, Inc.*, 649 F. Supp. 799, 803 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989).



vomiting can cause dehydration and acidosis, which can, if untreated, result in nutritional deficiencies, nerve damage, birth defects, and—in the worst cases—can threaten the life of the pregnant woman and her fetus. In short, the inability to obtain Bendectin has left a "significant therapeutic gap" in the treatment of morning sickness. See AMA Report, at 11.

The adverse impact of unfounded liability also has been keenly felt by manufacturers of contraceptives. Indeed, a recent study by the National Research Council and the Institute of Medicine concluded that product liability concerns "have contributed significantly to the climate of disincentives for the development of contraceptive products." National Research Council & Institute of Medicine, *Developing New Contraceptives—Obstacles and Opportunities* 141 (L. Mastroianni *et al.* eds., 1990). The study emphasized in particular the "unpredictable nature of litigation." *Id.*

The AMA also has documented the dramatic drop in basic research in this area:

> In the early 1970s, there were 13 pharmaceutical companies actively pursuing research in contraception and fertility. Now, only one US company conducts contraceptive and fertility research. Unless the liability laws are drastically altered, it is very unlikely that pharmaceutical companies will aggressively pursue research in this area.

AMA Report at 9.

The Copper-7 intrauterine device ("IUD") provides a striking case study of the effect of liability concerns on the availability of vaginal contraceptives. Use of this IUD involves a very slight risk of pelvic inflammatory disease. However, most physicians endorse the use of the product in appropriate patients, and the FDA still considers it to be "safe and effective." A number of federal courts, however, have allowed experts to offer opinions

without basis in scientific methodology suggesting that this IUD is far more dangerous than any legitimate study has demonstrated. See, *e.g.*, *Amore* v. *G.D. Searle & Co.*, 748 F. Supp. 845 (S.D. Fla. 1990). As a result, although the manufacturer prevailed in a number of cases alleging injury based upon the use of this IUD, see *id.* at 848 n.3, by 1986, it became impossible to purchase insurance for the product. Such a result is plainly contrary to the public interest—particularly, in light of established knowledge that IUD's are, in fact, the most effective and safest contraceptive option for some women, especially older women. See H. Cole ed., *Diagnostic and Therapeutic Technology Assessment (DATTA): Intrauterine Devices*, 261 JAMA 2127 (1989).

The admission of unscientific testimony also has affected the availability of many vaccines. Vaccines, particularly those for childhood diseases, "are one of the greatest success stories of medicine." AMA Report, at 6. Most domestic manufacturers, however, have stopped producing and distributing childhood vaccines. *Id.* More than half of the vaccine producers licensed in 1968 have ceased production, and this country is now "heavily dependent on sole suppliers" for many pediatric vaccines. Institute of Medicine, *Vaccine Supply and Innovation* ("*Vaccine Supply*") 5 (1985). The primary cause of this precipitous decline in vaccine production capacity has been "the liability situation and its consequences (*i.e.*, litigation costs or difficulty in obtaining insurance coverage)." *Id.* at 11.[13]

Here again, an example is illustrative. Thorough epidemiological studies have demonstrated that there is

[13] In some cases, Congress has been forced to adopt no-fault compensation systems in an effort to keep good vaccines available. *See* W. Mariner, *The National Vaccine Injury Compensation Program*, Health Affairs, Spring 1992, at 255, 259 ("[the program] was created to avoid disputes about whether a vaccine caused adverse reactions at all").



no statistically significant relationship between the vaccine for diphtheria, tetanus, and pertussis (whooping cough) and encephalopathy, an inflammatory brain disease. See M. Griffin *et al.*, *Risk of Seizures and Encephalopathy After Immunization With the Diphtheria-Tetanus-Pertussis Vaccine*, 263 JAMA 1641 (1990). Nonetheless, all but one manufacturer stopped making this vaccine following a series of lawsuits based upon unsubstantiated medical "opinion" that the pertussis portion of the vaccine might in fact be causing encephalopathy. See J. Cherry, *"Pertussis Vaccine Encephalopathy": It Is Time to Recognize It as the Myth That It Is*, 263 JAMA 1679 (1990); *Vaccine Supply*, at 27, 68.[14] As a result, the medical profession almost lost one of its most successful and widely used childhood vaccines.

In addition to threatening the supply of existing vaccines, the prospect of medically unfounded tort liability is retarding innovation. See, *e.g.*, FDA, "Biological Products: Bacterial Vaccines and Toxoids: Implementation of Efficacy Review," 50 Fed. Reg. 51002, 51006 (Dec. 13, 1985) ("attempts to improve vaccines further will be hampered" by tort liability); *Vaccine Supply*, at 11 ("apprehensions [concerning liability] are a disincentive to investment in the development of new (or improved) immunizing agents").[15] The prospect of undue

[14] One such suit was *Graham* v. *Wyeth Laboratories*, 906 F.2d 1399 (10th Cir.), *cert. denied*, 111 S. Ct. 511 (1990). In *Graham*, the plaintiff's experts testified that the "endotoxin content" of the vaccine was much higher than other vaccines on the market. As it turned out, the plaintiff's experts had grossly miscalculated the endotoxin content, which was ten times less than their estimate. The defendant, on the other hand, produced well-grounded medical evidence that the plaintiff's injuries actually were caused by a stroke weeks before the vaccine was administered. *Id.* at 1407-11 (reversing $15 million judgment against manufacturer).

[15] *See also Vaccine Injury Compensation: Hearing Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 115 (1986) (statement

liability also may be holding back the development of a vaccine for the AIDS virus. See J. Cohen, *Is Liability Slowing AIDS Vaccines?*, 256 Science 168 (Apr. 10, 1992).

Finally, unscientific judgments also have adversely affected the provision of medical services.[16] When unscientific testimony is introduced into evidence, it changes the deterrent signal of the tort system in a way that communicates to physicians that following sound medical practice will not protect them from liability. In particular, many obstetricians have been subject to successful tort claims attributing various ailments, including cerebral palsy, to their improper handling of deliveries and their failure to perform cesarean sections. See, *e.g.*, *Low* v. *United States*, 795 F.2d 466 (5th Cir. 1986); *Nemmers* v. *United States*, 612 F. Supp. 928 (C.D. Ill. 1985), *vacated on other grounds*, 795 F.2d 628 (7th Cir. 1986); see also N. Rhoden, *The Judge in the Delivery Room: The Emergence of Court-Ordered Cesareans*, 74 Cal. L. Rev. 1951, 2010-23 (1986). As a result of such claims, malpractice premiums for obstetricians and family physicians who practice obstetrics have skyrocketed, driving many such physicians out of that practice, especially in rural areas. See American College of Obstetricians and Gynecologists, *Professional Liability Insurance and Its*

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of Dr. Martin H. Smith, President, American Academy of Pediatrics) ("research efforts for new and improved vaccines have been chilled" because of liability concerns).

[16] Fear of uncertain liability also causes physicians to practice "defensive medicine"—*i.e.*, the provision of additional tests, procedures, services and recordkeeping that are justified more by the need to defend clinical decisions in the microscopic hindsight of malpractice litigation than by a wholly objective assessment of the patient's diagnostic or therapeutic needs. As long as the law allows theories of liability to be supported by unscientific opinion in the guise of expert testimony, the deterrent effect of tort liability is distorted causing physicians to practice defensive medicine, with the inevitable increase in health care costs.



*Effects; Report of a Survey of ACOG's Membership* (1992).

The available scientific evidence, however, provides no support for the hypothesis that cerebral palsy results from improper delivery techniques. Indeed, it is increasingly clear that obstetricians have virtually no ability to prevent cerebral palsy through either the use of electronic fetal monitoring devices or more frequent cesarean sections. See K. Shy *et al.*, *Effects of Electronic Fetal-Heart-Rate Monitoring, as Compared with Periodic Auscultation, on the Neurologic Development of Premature Infants*, 322 New Eng. J. Med. 588 (1990). In fact, the medical consensus is that too many cesarean sections are now performed in the United States. See S. Myers & N. Gleicher, *A Successful Program to Lower Cesarean-Section Rates*, 319 New Eng. J. Med. 1511 (1988).

In short, the admission of unscientific medical "opinion" furthers no legitimate scientific, legal or social purpose. To the contrary, if opinions that lack a scientific foundation are admitted into evidence, then some judgments inevitably will be based on those opinions. And, as a result, the practice of medicine will be influenced by these judgments, to the detriment of the health of the public. Such a perverse result is at odds with the goals of the Federal Rules of Evidence and of the judicial process itself, and makes the law the enemy of good science.

To be sure, the law will always remain something of a mystery to professionals in other disciplines, just as the nuances of science will lie beyond the competence of most attorneys. But the law loses credibility in the eyes of physicians and other scientists when it imposes liability, or even the risk of liability and the burdens of trial, on the basis of evidence that lacks serious scientific merit. Those trained in science and medicine quite rightly have little respect for the workings of the law if it does nothing more than transfer resources from one party to an-

other without regard to the basic methodologies and common understanding of scientific practitioners.

In particular, liability imposed on physicians on the basis of unscientific testimony will cause some practitioners to stop providing services that, while medically indicated, involve a high risk of suit. Similarly, it will cause practitioners to seek "diagnostic certainty" and provide excessive services, thereby adding unnecessary billions of dollars to the cost of medical care. Rule 702 does not require such harmful consequences. To the contrary, the Rule's language and structure evince an intent to promote the truth-finding process both inside and outside the courtroom by requiring expert opinion to be based on scientifically accepted methods.

## III. THE NINTH CIRCUIT CORRECTLY EXCLUDED THE TESTIMONY PROFFERED BY PETITIONERS' EXPERTS IN THIS CASE.

More than 30 rigorous, controlled, and reviewed studies have been conducted to determine whether there is a statistically significant correlation between the use of Bendectin and an increase in the incidence of birth defects. None of these studies found any such correlation. Thus, they tend strongly to disprove the hypothesis that Bendectin causes birth defects. Because these studies were performed according to the standards of science, their conclusions contribute to medical knowledge. These studies therefore are admissible under Rule 702.

On the other hand, not one peer-reviewed study has been published that demonstrates the existence of any statistically significant association between Bendectin and limb defects. Given the significant attention that the scientific community has paid to this issue, the absence of any such published findings strongly supports the court of appeals' conclusion that the opinions offered by petitioners' experts simply lack sufficient scientific bases to permit the introduction of those opinions into evidence,



The "reanalysis" of the epidemiological studies proffered by petitioners' experts in this case did not conform to the standards of the scientific method.[17] As the district court stated, Dr. Adrian Gross recalculated the data in existing epidemiological studies. He did not publish his calculations or subject them to the scrutiny of other scientists through the process of peer review. "Nowhere does [Dr. Gross's study] state that Bendectin sales increased the relative risks of limb reduction defects to a level significantly above 1.0 with a confidence interval that did not include unity." JA 236. In other words, even Dr. Gross did not find a statistically significant difference. The same is true of all of petitioners' remaining experts. JA 232-36. The opinions of these experts therefore were not based upon "scientific knowledge." Therefore, the court of appeals properly upheld the district court's exclusion of their testimony.

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The touchstone of Rule 702 is scientific knowledge. Under this Rule, expert scientific testimony must adhere to the recognized standards of good scientific methodology including rigorous analysis, accurate and statistically significant measurement, and reproducibility. One helpful, but not dispositive, indication that knowledge has a scientific basis is the existence of published, peer-reviewed

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[17] "Reanalysis" or "meta-analysis" of existing epidemiological data—when properly conducted and reviewed—may be an acceptable scientific methodology. *See* H. Kahn & C. Sempos, *Statistical Methods in Epidemiology* 8-11 (1989); O. Miettinen, *Theoretical Epidemiology* 109-15 (1985); T. Colton, *Statistics in Medicine* 99-146 (1974). Indeed, a "meta-analysis" may find statistical significance across a range of studies where no individual study found a statistically significant result. *See* H. Sacks *et al.*, *Meta-Analyses of Randomized Control Trials*, in *Medical Uses of Statistics* 427-41 (J. Bailar & F. Mosteller eds., 2d ed. 1992). However, there is no indication that a statistically valid meta-analysis—*i.e.*, a meta-analysis performed in accordance with scientific methodology—was performed by any of the expert witnesses proffered by petitioners.

studies supporting it. When expert testimony is not based on peer-viewed studies and is not otherwise based upon information acquired through the scientific method is admitted into evidence, there is a risk that judgments will be based on such testimony and that scientific professionals will alter their behavior accordingly. As applied to the medical profession, deviations from science ultimately have an adverse effect on public health, as this case well illustrates. The Federal Rules of Evidence were never intended to, and should not be interpreted to, place the rules of law and science at odds with one another.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

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January 19, 1993

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## APPENDIX

The American Academy of Allergy and Immunology was organized as a nonprofit society in 1943 and has since become the largest national professional medical society in the field of allergy, clinical immunology and related diseases. It represents 4,600 physicians and allied health professionals in the United States, Canada, and 41 foreign countries. Its purposes are to advance the practice of immunology, to foster the education of both students and the public, and to promote cooperation among those engaged in the fields of allergy and immunology.

The American Academy of Dermatology is the largest professional association of physicians specializing in dermatology. Its primary goals are to promote and advance the science and art of medicine and surgery related to the skin, hair, nails and mucous membranes and promote the highest possible standards in clinical practice, education and research in dermatology and related disciplines.

The American Academy of Family Physicians is a private, voluntary, non-profit organization of physicians, with a membership of more than 74,000 family physicians and medical students. Included among the Academy's objects and purposes are to preserve and promote quality cost-effective health care and to provide responsible advocacy for and education of patients and the public in all health-related matters.

The American Academy of Orthopaedic Surgeons is the primary educational and professional organization of orthopaedic surgeons in the United States. Founded in 1933, the Academy is an Illinois not-for-profit corporation whose Fellowship includes nearly 18,500 orthopaedic surgeons, approximately 96% of the board-certified orthopaedic surgeons in the United States.

The American Academy of Pain Medicine is a not-for-profit organization with over 600 physician members. The

Academy is dedicated to pursuing excellence in education as it concerns Pain Medicine and related sciences, and to upholding high principles, policies and practices for the attainment of the best in care for the patient suffering with pain.

The American Academy of Neurology is a nonprofit organization of over 11,000 neurologists and neuroscientists throughout the United States and abroad, and is the only medical organization that speaks for all of neurology. Neurologists are committed to the treatment and research leading to cures for disorders of the nervous system—the brain, spinal cord and nerves. The Academy is equally committed to fostering the educational and professional advancement of its members and supports efforts to ensure that the integrity of this profession is maintained.

The American Association of Neurological Surgeons is a private, voluntary non-profit organization of neurosurgeons. The Association was founded in 1931 as The Harvey Cushing Society to: (1) promote optimum quality in the delivery of neurosurgical care, while maintaining cost-effectiveness; (2) provide relevant and significant education programs for the neurosurgical community; (3) promote research in the neurosciences. Today, its membership of nearly 3,800 includes Board-certified neurosurgeons, as well as individuals who have shown distinction in many related medical disciplines.

The American College of Obstetricians and Gynecologists is a private, voluntary, non-profit organization of physicians who specialize in obstetric and gynecologic care. The College is the leading group of professionals providing health care to women; its 32,000 members represent approximately ninety percent of all obstetricians and gynecologists practicing in the United States. Obstetricians and gynecologists are the most frequently sued of all the speicalities, with approximately 80% of the College's members having experienced at least one medical liability suit. For such a high-risk specialty, it is especially important that medical expert testimony used in litigation be scientifically valid.



The American College of Pain Medicine was formed in 1991 as an educational not-for-profit corporation. Its purpose is to act as an educational association of physicians (Doctors of Medicine, Doctors of Osteopathy), to conduct examinations and to award Fellowship certification in the medical specialty of pain medicine.

The American College of Physicians is a private, voluntary, nonprofit organization of physicians trained in internal medicine, and diagnosis and nonsurgical treatment of disease and illness in adults and young adults. The College is the nation's largest medical specialty society, with more than 77,000 members who include practitioners providing primary care; medical specialists in fields such as cardiology, neurology, and oncology; and medical researchers and educators. Founded in 1915 to uphold high standards in medical practice, education, and research, the College continues to strive to meet those goals and has more recently added practice standard-setting; technology assessment; and health policy, ethical, and medical-legal issues analysis to its activities.

The American College of Radiology, which was founded in 1923, is the principal organization of radiologists in the United States, with more than 28,000 members. The College is a non-profit membership association whose principal purposes are to advance the science of radiology, improve services to the patient, and encourage continuing education for radiologists and persons practicing in allied professional fields.

The American Society of Anesthesiologists is a voluntary not-for-profit New York corporation. The Society has an active membership of over 20,000 physicians or other scientists practicing or especially interested in the specialty medical practice of anesthesiology.

The American Society of Plastic and Reconstructive Surgeons is a private, voluntary, non-profit organization

of board-certified plastic surgeons founded in 1931. The mission of the Society is to promote optimal care for plastic surgery patients through education, research and high professional standards, and to support its members' socioeconomic and professional activities. The Society represents approximately 5,000 board-certified plastic surgeons in the United States and Canada.

The American Urological Association is a private, voluntary, non-profit organization of urologists. The Association was founded in 1902 to be the professional organization which fosters the highest standards of urologic care through education, research and the representation of the membership in formulation of health care policy. The current membership is 8,830 urologists around the world.

The College of American Pathologists is a national medical specialty society serving more than 13,000 members and the laboratory community. The College offers member services, quality assurance programs, and management resources designed to enhance pathology practice for its members and to improve laboratory services for physicians and the public.